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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,164	04/01/2004	Esther Regina de Rooij	2183-6412US	1592

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,164	DE ROOIJ ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *28-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed April 1, 2004 is acknowledged and entered. Claims 1-35 are pending. The instant application was placed in special status on December 21, 2004.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to a method of detecting a nucleic acid, classified in class 435, subclass 4.

II. Claims 28-35, drawn to a carrier, classified in class 424, subclass 280.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process of use, such as in an assay for quantifying and purifying antibodies, wherein the carrier displays an antigen to which the antibodies bind. A search for the method of Group I may reveal different carriers than those claimed in Group II. Likewise, literature that speaks to the carriers will not necessarily reveal the method claimed in Group I. Therefore, a search for both Groups would be a serious burden of search and examination on the examiner.

Because these inventions are distinct for the reasons given above and the literature search required for Group I is not required for Group II, and therefore a serious burden, restriction for examination purposes as indicated is proper.

During a telephone conversation with Allen Turner on June 7, 2005, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

3. Claim 27 objected to because of the following informality: The claim lacks a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "precious" in claim 20 is a relative term that renders the claim indefinite. The term "precious bodily fluid" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is subject to individual interpretation. If Applicant cannot point to an indisputable definition of "precious bodily fluid" in the specification, then Applicant is advised to delete the word, "precious" in order to overcome this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7, 10, 14-18, 20-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yourno *et al.* (*Journal of Clinical Microbiology*, 1992, 30(11):2887-2892, "Yourno"). The claims are drawn to a process for detecting a nucleic acid of interest in at least one sample, comprising administering the sample to a solid carrier that absorbs the sample, drying the solid carrier, extracting a representative part of the sample from the solid carrier with a nucleic acid isolation solution and detecting the nucleic acid of interest. A further step is quantification and identification of detected nucleic acid. A known amount of nucleic acid is

added to the carrier. Also claimed is the detection of HIV-1. The sample comprises a droplet of whole blood or plasma.

Yourno a polymerase chain reaction method for detecting HIV in dried blood spots on filter paper. Fifty microliters of HIV-1-infected blood was spotted on standard newborn screening filter paper. A known amount of HIV was infected into the cells (page 2887, second column, line 4). The whole blood spots (comprised of droplets) were dried and punched. The punches were suspended in lysis buffer and analyzed by PCR, which an end-point read-out system (page 2887, abstract and Materials and Methods section). PCR detected the nucleic acid and yield (Figure 1). Regarding the limitation of claim 23, Yourno's blood sample contains plasma. Note that the claim does not limit the sample to plasma, merely the presence of plasma ("comprising", open claim language). The limitation of claim 10 requires that the representative part of the solid carrier comprise one of the samples, which Yourno's filter does. Therefore, the methods of claims 1, 2, 5, 7, 10, 14-18, 20-24 and 26 are anticipated by Yourno.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, 6, 8, 9, 11-13, 19, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yourno, as applied to claims 1, 2, 5, 7, 10, 14-18, 20-24 and 26 above, and further in view of Gillespie (US 5,482,834) and Higuchi *et al.* (*Bio/Technology*, 1993, 11:1026-

1030, "Higuchi"). The claims are drawn to limitations wherein two different samples are adsorbed to the carrier, wherein 100 or 250 microliters of a sample are applied to the solid carrier, wherein the entire sample/carrier is the representative part of the carrier, wherein the lysis buffer is chaotropic and wherein the method further comprises the step of genotyping a mutant from which the nucleic acid of interest originates. Further, the method identifies RNA nucleic acid, specifically mitochondrial RNA, viral RNA, messenger RNA and combinations thereof. The amplification is real-time monitored amplification. Yourno fails to teach these limitations.

Higuchi discloses a real-time monitoring of DNA amplification reactions. It would have been obvious to use real-time PCR with Yourno's method. One would have been motivated to use real-time PCR for Yourno's PCR method because Higuchi discloses that real-time PCR analysis permits sensitive, quantitative detection of DNA sequences over a wide dynamic range, compared to end-point read-outs (page 1029, Discussion section). One would have had a reasonable expectation of success that real-time PCR would have worked in Yourno's method of detection because Yourno also uses PCR, however it is an end-point read-out PCR method.

Gillespie discloses the use of a chaotropic salt solution along with nucleic acid probes to improve hybridization of probes with their targets (abstract). Gillespie teaches that a chaotropic salt dissolves a biological source of RNA, such as cells and bacteria (col. 6, line 65 through col. 7, lines 1-13). The salts are also used to expose DNA from its sources (col. 8, lines 19-47). It would have been obvious to use the chaotropic salts suggested by Gillespie in the method of Yourno. One would have been motivated to use the chaotropic salts to improve the hybridization in Yourno's method of probes to nucleic acid. One would have had a reasonable expectation of

success that the addition of chaotropic salts to Yourno's method would have improved hybridization because Gillespie's salts are useful in methods of detecting HIV nucleic acid in blood (Examples 16 and 17).

The other aspects of the invention not taught by Yourno are obvious in view of the process of optimization. One would have been motivated to optimize Yourno's process by taking blood samples from the same person but at different times for a more comprehensive diagnosis. For example, blood taken from a person at day 0 may yield different results from blood taken at day 7. The blood is taken at separate times, but is spotted at the same time on different places on the filter paper. If several blood samples are spotted on the filter, the total amount of blood is expected to be greater than Yourno's 50 microliters, reaching to 100 or 250 microliters, depending on the number of drops on the filter paper. Regarding the use of the whole sample on the carrier, this is an obvious optimization step of Yourno's method. The use of the whole sample would be appropriate if the area of filter paper was tailored to absorb exactly one drop that is flush with the end of the filter paper, or if the materials for the lysing and detecting steps were large enough to accommodate a large filter paper that is completely sample-filled. Further, the claim language does not specify the size of the filter paper, so a "whole" punch-out itself is encompassed by claim 9, "carrier comprises the whole of the solid carrier".

Regarding the step of genotyping a mutant from which the nucleic acid originates, this step is also an obvious optimization of Yourno's method. One would expect that mutants naturally exist in a patient's blood, especially with viruses such as HIV which mutate rapidly. Performing Yourno's method or Gillespie's method would be expected to result in the

genotyping of an HIV mutant. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

7. No claim is allowed. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-

272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
June 17, 2005